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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/377,502	08/20/99	PAUL W	1012/60036/J

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EXAMINER	
FOX, D	

ART UNIT	PAPER NUMBER
1638	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/377,502	PAUL ET AL.	
	Examiner	Art Unit	
	David Fox	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *3,4,7,10,11,17,18,21,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,8,9,12-16,19,20,22,23 and 26-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,7,10* .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Applicant's election with traverse of Group I in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the different inventions are not independent and would not require serious search burdens. This is not found persuasive because distinctness alone, in addition to independence, is a proper ground for restriction, as stated in the last office action. Furthermore, each invention involves a different structural gene and resultant phenotype, thus requiring different searches, as stated in the last office action.

The requirement is still deemed proper and is therefore made FINAL.

Based upon Applicants' arguments regarding the generic nature of the claims, the Restriction Requirement of 13 December 2000 is hereby recast as an election of species requirement.

This application contains claims directed to the following patentably distinct species of the claimed invention:

I. Genes encoding non-functional portions of an enzyme such as an enzyme involved in carbohydrate biosynthesis, and plants transformed therewith (Claims 1-2, 5-6, 8-9, 12-16, 19-20, 22-23 and 26-30).

II. Genes encoding proteins involved in male sterility and plants transformed therewith (Claims 3-4, 7, 10-11, 17-18, 21 and 24-25).

III. Genes encoding proteins involved in embyroless seed production and plants transformed therewith (Claims 3, 7, 11, 17, 21, and 25).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 5-9, 11-17, 19-23 and 25-30 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants' election of Group I in Paper No. 9 has been treated as a response to the above election of species requirement. Note that claim 30 is now included in elected Species I.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite in its recitation of "gene sequence[s]...is transgenic" which is contrary to art-recognized usage, as "transgenic" refers to the recipient organism while --transgene-- refers to the introduced gene itself.

Claim 29 is indefinite in its recitation of "seed or plant obtainable from a pair of plants" as it is unclear how a single plant can be obtained from a pair of plants. Furthermore, it is unclear whether the seed is derived from crossing both plants of the pair, or whether the seed is generated by selfing one of the plants. In addition, "obtainable" does not positively recite a required claim element. If the products of the cross of the two plants of the pair were intended, the claim should be rewritten as follows:

--A seed obtained by crossing the pair of plants of claim 1, or a plant obtained from said seed--.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-16 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lloyd et al.

Lloyd et al teach a method for producing a plant having the phenotype of intense pigmentation in above-ground portions and some pigmentation in the roots, said method comprising crossing a first tobacco or Arabidopsis plant containing a heterologous maize R gene with a second tobacco or Arabidopsis plant containing a heterologous maize C1 gene, wherein the R and C1 gene each encode proteins that individually do not confer below-ground pigmentation or above-ground pigmentation to the degree that the plants grown from the seed products of the cross exhibit (see, e.g., page 1773, paragraph bridging columns 2 and 3, and first full paragraph of column 3; paragraph bridging pages 1773 and 1774).

Claims 15-16, 26 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Krizek et al.

Krizek et al teach a method for producing a plant having the phenotype of two whorls of petals, earlier flowering, and some conversion of leaves to petals, said method comprising crossing a first Arabidopsis plant, containing a heterologous APETALA3 gene ligated to a sequence encoding a beta-glucoronidase carrier protein, with a second Arabidopsis plant, containing a heterologous PISTILLATA gene, wherein the AP3 and PI genes each encode proteins that do not individually confer the above phenotypes to the original parent plants (see, e.g., page 12, column 1, first full paragraph of column 2; paragraph bridging pages 12 and 13; page 13, column 1, first full paragraph; page 17, column 2, bottom paragraph).

Claims 1-2, 9, 14-16, 23, and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 91/09957 (DUPONT).

DUPONT teaches a method for obtaining a plant with the phenotype of antibiotic resistance via the expression of a functional neomycin phosphotransferase enzyme, said method comprising crossing a first plant, containing a *cre* transgene encoding a recombinase which recognizes *loxP* sites, with a second plant, containing a transgene encoding a neomycin phosphotransferase but interrupted by a polyadenylation signal bounded by two *loxP* sites, wherein the first and second plants are homozygous for said transgenes, wherein the first and the second plant each contain protein-encoding genes but neither the first nor the second plant exhibit the desired phenotype or possess proteins which are solely responsible for the desired phenotype, wherein said method is useful for controlling the environmental exposure of antibiotic marker proteins (see, e.g., page 17, line 30 through page 18, line 18; pages 39-59).

Claims 1-2, 9, 12, 14-16, 23, 26 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/20668 (NICKERSON).

NICKERSON teaches a method for obtaining a plant with the phenotype of blue staining due to the presence of a functional beta-glucoronidase protein, said method comprising crossing a first plant, containing a transgene encoding a phage T7 RNA polymerase, with a second plant, containing a transgene comprising the phage T7 promoter and a sequence encoding a fusion protein comprising the carrier protein encoded by the tobacco etch virus leader sequence and the GUS protein, wherein the first and second plant are homozygous for the transgenes, and wherein

the first and second plant each contain protein-encoding genes but neither the first nor the second plant exhibit the desired phenotype or possess proteins which are solely responsible for the desired phenotype (see, e.g., pages 18-20 and 46-49).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-16, 19, 23, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lloyd et al.

Lloyd et al teach a method for producing a plant having the phenotype of intense pigmentation in above-ground portions and some pigmentation in the roots, said method comprising crossing a first tobacco or Arabidopsis plant containing a heterologous maize R gene with a second tobacco or Arabidopsis plant containing a heterologous maize C1 gene, wherein the

R and C1 gene each encode proteins that individually do not confer below-ground pigmentation or above-ground pigmentation to the degree that the plants grown from the seed products of the cross exhibit, as discussed above.

Lloyd et al do not teach parent plants homozygous for the R or C1 genes, the use of tissue-specific promoters, or the use of carrier protein-encoding sequences or transit peptide-encoding sequences.

It would have been obvious to one of ordinary skill in the art to utilize the method for obtaining a desired phenotype as taught by Lloyd et al, and to modify that method by incorporating known tissue-specific promoters or transit peptides, and to further modify that method by incorporating selfing of the parents to ensure homozygosity; given the recognition by those of ordinary skill in the art of the advantages of tissue-specific gene expression for controlled phenotypic change, and given the recognition by those of ordinary skill in the art of the advantages of homozygosity of parent lines for increasing the likelihood that genes of interest will be transmitted through the gametes.

Claims 15-16, 19, 23, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krizek et al.

Krizek et al teach a method for producing a plant having the phenotype of two whorls of petals, earlier flowering, and some conversion of leaves to petals, said method comprising crossing a first Arabidopsis plant, containing a heterologous APETALA3 gene ligated to a sequence encoding a beta-glucoronidase carrier protein, with a second Arabidopsis plant,

containing a heterologous PISTILLATA gene, wherein the AP3 and PI genes each encode proteins that do not individually confer the above phenotypes to the original parent plants, as discussed above.

Krizek et al do not teach tissue-specific promoters or homozygosity for the parental lines' gene of interest.

It would have been obvious to one of ordinary skill in the art to utilize the method for obtaining a desired phenotype as taught by Krizek et al, and to modify that method by incorporating known tissue-specific promoters, and to further modify that method by incorporating selfing of the parents to ensure homozygosity; given the recognition by those of ordinary skill in the art of the advantages of tissue-specific gene expression for controlled phenotypic change, and given the recognition by those of ordinary skill in the art of the advantages of homozygosity of parent lines for increasing the likelihood that genes of interest will be transmitted through the gametes.

Claims 1-2, 5, 9, 12, 14-16, 19, 23, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/09957 (DUPONT).

DUPONT teaches a method for obtaining a plant with the phenotype of antibiotic resistance via the expression of a functional neomycin phosphotransferase enzyme, said method comprising crossing a first plant, containing a *cre* transgene encoding a recombinase which recognizes *loxP* sites, with a second plant, containing a transgene encoding a neomycin phosphotransferase but interrupted by a polyadenylation signal bounded by two *loxP* sites,

wherein the first and second plants are homozygous for said transgenes, wherein the first and the second plant each contain protein-encoding genes but neither the first nor the second plant exhibit the desired phenotype or possess proteins which are solely responsible for the desired phenotype, wherein said method is useful for controlling the environmental exposure of antibiotic marker proteins, as discussed above.

DUPONT does not teach the use of a tissue-specific promoter or a carrier protein or transit peptide.

DUPONT suggests the use of tissue-specific promoters for the modification of traits of interest such as seed oil content or the carbohydrate content of seeds or fruit (see, e.g., page 4, lines 26-34; page 13).

It would have been obvious to one of ordinary skill in the art to utilize the method for obtaining a desired phenotype as taught by DUPONT, and to modify that method by incorporating known tissue-specific promoters and/or transit peptide-encoding sequences; given the recognition by those of ordinary skill in the art of the advantages of tissue-specific gene expression for controlled phenotypic change, and the suggestion to do so by DUPONT.

Claims 1-2, 5, 9, 12, 14-16, 19, 23, 26 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/20668 (NICKERSON).

NICKERSON teaches a method for obtaining a plant with the phenotype of blue staining due to the presence of a functional beta-glucoronidase protein, said method comprising crossing a first plant, containing a transgene encoding a phage T7 RNA polymerase, with a second plant,

containing a transgene comprising the phage T7 promoter and a sequence encoding a fusion protein comprising the carrier protein encoded by the tobacco etch virus leader sequence and the GUS protein, wherein the first and second plant are homozygous for the transgenes, and wherein the first and second plant each contain protein-encoding genes but neither the first nor the second plant exhibit the desired phenotype or possess proteins which are solely responsible for the desired phenotype, as discussed above. NICKERSON also suggests the advantages of tissue-specific expression of genes of interest (see, e.g., page 49, lines 2-4).

NICKERSON does not teach the use of a tissue-specific promoter with the above system.

It would have been obvious to one of ordinary skill in the art to utilize the method for obtaining a desired phenotype as taught by NICKERSON, and to modify that method by incorporating known tissue-specific promoters and/or transit peptide-encoding sequences; given the recognition by those of ordinary skill in the art of the advantages of tissue-specific gene expression for controlled phenotypic change, as suggested by NICKERSON.

Claims 1-2, 5-6, 8-9, 12-16, 19-20, 22-23 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/00789 (ALKO GROUP) taken with WO 93/17093 (OY ALKO AB) and Hiatt et al (1989).

ALKO GROUP teaches the transformation of plants with genes encoding yeast proteins involved in the synthesis of trehalose, including the trehalose phosphate synthase gene and the trehalose phosphate phosphatase genes, wherein the introduction of both genes results in high levels of trehalose production, particularly in plants that do not possess high levels of native

phosphatase activity, and wherein most plants do not possess either trehalose synthesis enzyme or the ability to synthesize trehalose. ALKO GROUP also teach that each trehalose synthesis enzyme is comprised of individual subunits and is subject to regulation by another gene, and that trehalose production increases the structural integrity of cell membranes and contributes to cold tolerance and drought tolerance, but may cause some deleterious effects on plants which are not exposed to these conditions. ALKO GROUP also suggests the use of tissue-specific promoters for the controlled expression of the trehalose biosynthesis genes in order to sequester the product into the organs which require it, while avoiding the deleterious effects on plant growth in general. ALKO GROUP also suggest the use of cross-breeding to introduce the individual trehalose biosynthesis or regulatory genes, each present in an individual parent which is unable to synthesize trehalose, into a progeny plant which would possess all working proteins and synthesize trehalose. See, e.g., pages 1-5, 7, 9, 11-13, 16-18, 21-22, 26-28 and 31-32.

ALKO GROUP does not actually teach the crossing of plants each containing individual trehalose biosynthesis genes or genes encoding subunits thereof, the use of transit peptides or carrier peptides, artificially split enzymes, homozygosity of the parents, or protein dimerization regions.

OY ALKO AB teaches that each yeast trehalose biosynthesis enzyme is comprised of subunits encoded by different genes, the existence of a regulatory protein encoded by yet another gene, and the ability of trehalose to confer stress tolerance to organisms containing it; and

suggests plant transformation therewith for tissue-specific accumulation of trehalose (see, e.g., pages 8-9, 16-21, 40-46, 48-58, 69-70, 72-76 and 79-80).

Hiatt et al (1989) teach the use of targeting sequences for the increased stability of subunits of dimeric proteins to be assembled in plants, as well as the advantages of crossing parent plants each containing a single subunit-encoding gene (see, e.g., page 77, bottom paragraph of each column).

It would have been obvious to one of ordinary skill in the art to utilize the method of plant transformation with individual trehalose biosynthesis genes, followed by the combination of each gene into a single plant, for the production of trehalose-producing plants containing active trehalose biosynthesis enzymes and exhibiting a stress-tolerant phenotype not present in the parent plants, as taught by ALKO GROUP; and to modify that method by incorporating the genes encoding the individual subunits of each trehalose biosynthesis enzyme or regulatory protein as taught by OY ALKO AB, and to further modify that method by incorporating sexual crossing rather than sequential or co-transformation as suggested by ALKO GROUP and Hiatt et al, in order to limit the potentially growth-retardant production of trehalose to those hybrid plants which exhibit other desirable characteristics or possess otherwise desirable genotypes, as suggested by ALKO GROUP. Furthermore, it would have been obvious to incorporate tissue-specific promoters and carrier peptides or transit peptides as suggested by ALKO GROUP, OY ALKO AB, and Hiatt et al. In addition, it would have been obvious to incorporate other well-known sequences such as dimerization domains for facilitating the assembly of the two individual

subunits, as suggested by Hiatt et al. The use of homozygous parents to increase the likelihood of transmission of the desirable gene through the gamete is well known, as discussed above. Finally, choice of naturally occurring subunit or artificially split enzyme would have been the optimization of process parameters.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 21, 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638